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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,559	11/19/2003	Chon-Ho Yen	YENC3003/EM	5053
23364	7590	02/22/2006	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			MENON, KRISHNAN S	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,559

Applicant(s)

YEN ET AL.

Examiner

Krishnan S. Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-32 are pending as originally filed

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 11, 12, 13, 21 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim 11 recites "any of the methods as stated in claim 1". Claim 1 states only one method – filtering through a filter. For examination purpose, claim is assumed to read "the method" in place of "any of the methods".

Claim 13 and 30: "for the purpose of condensing the target substance": Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "condensing" in claim 13 and 30 is used by the claim to mean

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“concentrating”, while the accepted meaning is “change from a vapor state to a liquid state.” The term is indefinite because the specification does not clearly redefine the term.

Claim 21: ‘holes of the ... membrane is 30kD’ is indefinite because “kD” is a measure of molecular weight of polymers. The claim is assumed to mean “membrane has a molecular weight cut-off of 30kD”.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: no specific steps are given to purify the target substance peptide or protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1,3-5,7, and 10-12 are rejected under 35 U.S.C. 102(b) as anticipated by Dieu et al (US 4,897,277).

Dieu teaches a method of filtering milk using a ceramic filter (figures, column 1 lines 58-67) to remove casein. The filter has porosity in the range 0.2-5 μm (column 2 lines 63-66). The milk is animal milk because, typically cow milk is used in the dairy

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industry. The system has an inherent pH value; claim does not recite adjusting pH to any specific value.

Re pressure of 10-20 psi, the system of the reference is capable of providing such pressures – see column 2 lines 19-23, 40-45, and column 2 line 67 – column 3 line 6. Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986)

Claim 7: variation of pH depending on the target protein is inherent in the system – property of the protein. Claim does not recite adjusting the pH to any specific value.

Claim 11 and 12: the process of the reference also purifies other target proteins – it separates milk proteins and casein from the milk. Column 1 lines 58-67.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dieu as applied to claim 1 above, and further in view of Holm et al (US 4,876,100).

The reference differs from the instant claims in the recital of a pretreatment process, centrifugal. However, centrifugal process for removing/separating fat from milk is well known. Holm teaches using centrifugal methods of separating fat from milk for producing skim milk and as a pre-treatment for sterilizing milk (see column 1 lines 20-28 and column 2 lines 38-45). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Holm in the teaching of Dieu for sterilizing milk or for using skim milk for cheese making.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dieu as applied to claim 1 above, and further in view of Mahmoud et al (US 6,051,268).

Claim 6 differs from the teaching of Dieu in the 'diafiltration'. Mahmoud teaches that it is conventional to use diafiltration method to remove salts and lactose from milk to concentrate proteins to high purity. It would be obvious to one of ordinary skill in the art at the time of invention to use 'conventional methods' for purifying proteins obtained from milk.

4. Claims 1,3-5 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687).

Denman teaches a method of filtering animal milk to separate casein by adjusting the pH to a certain value, like 5 (column 5 line 62 - 6 line 32), and using a filter of pore size 0.2-5 μm (column 7 line 50-65). Centrifugal pre-treatment is taught in the examples. Animal is transgenic – column 4 lines 33-43. Denman differs from the

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claims in the recitation of the 10-20 psi pressure for filtration. However, it would be obvious to one of ordinary skill in the art at the time of invention to provide adequate operating pressure for the filtration process. A prima facie case under 35 U.S.C. 102 /103 could be made if a process step is inherent: *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern" All the process limitations were expressly disclosed by a U.S. patent to Hansford except the cooling step. The court stated that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling.

5. Claims 13-16,22-28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268).

Denman teaches a method of separating and purifying casein, proteins, peptides or human coagulation factor IX from animal milk (column 3 lines 29-62, column 4 lines 25-32, column 5 lines 15-20) comprising adjusting pH to 5 by a buffer (column 5 line 62 – column 6 line 32), plurality of techniques including filtration and chromatography (column 7 lines 6-40), (column 7 lines 42-65), with chromatographic method for further purifying the target substance (column 7 lines 6-40). Animals are transgenic (column 4 lines 33-43).

Claims differ from the teaching of the reference in the recitation of the two separate filtration steps, fat removal by centrifugation and the diafiltration mode. Even if Denman teaches plurality of techniques including filtration, it is not specific about having two separate filtration steps. Multiple filtration steps are taught by Mahmoud for fractionating and separating components of milk such as casein (column 5 lines 59-67), and proteins by molecular weight (column 7 lines 25-60). Mahmoud teaches Fat removal by centrifugation and Diafiltration mode is taught as conventional (see column 1 lines 38-45). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Mahmoud in the teaching of Denman to fractionate the milk protein as desired by the various filtration steps as taught by Mahmoud.

With respect to the operating pressure of 10-20 psi, inherent process step – in re Best.

6. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268) as applied to claim 13 above and further in view of Dieu.

Instant claims differ from the teaching of Denman in view of Mahmoud in the ceramic membrane, which is taught by Dieu as in claim 1 above (paragraph 1). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Dieu in the teaching of Denman in view of Mahmoud because of the advantages of ceramic filter such as easy to clean and sterilize, commercial availability, etc. (see Dieu: column 1 lines 35-57 and column 4 lines 30-46)

7. Claims 20-21 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Denman et al (US 5,756,687) in view of Mahmoud et al (US 6,051,268) as applied to claim 13 above in paragraph 5 and Roesink et al (US 4,798,847).

Claims 20-21 and 30-32 differ from the material of the second membrane – polysulfone. However, Denman teaches that any material suitable for filtering milk could be used for the process. Roesink teaches polysulfone hydrophilic ultrafiltration membranes (column 1 lines 25-37 and column 2 lines 41-45) specifically made for applications such as milk and dairy products, blood, etc (column 1 lines 47-51). One would use the Roesink membrane because of its high temperature stability, chemical resistance and mechanical strength, suitable for proper sterilization, and because they can be made flat sheet, hollow fiber or tubular (see Roesink column 2 line 65 – column 3 line 9). Molecular weight cut off can be optimized as taught by Mahmoud – see column 7 lines 26-60 of Mahmoud.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'K S Menon', written in a cursive style.

Krishnan S. Menon
Patent Examiner
2/20/06